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10/564,322	06/26/2006	Kai Desinger	3444	8850

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EXAMINER	
DICICCO, JOHN R	

ART UNIT	PAPER NUMBER
3709	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,322	DESINGER ET AL.	
	Examiner	Art Unit	
	John R. Di Cicco	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 June 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/11/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the non-provisional application filed on June 26, 2006. Claims 1-12 are pending. Claim 1 is independent.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: #10 (mentioned on page 6) and #58 and #62 (mentioned on page 9). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because non-English language is used in Figures 3 and 5. The applicant should either remove the words from the drawings or write the English equivalent. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any

amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, with respect to claim 9, the hollow body having a smaller diameter in the region of the insulator and the distal electrode than in the region of the proximal electrode must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because the legal phraseology "said" has been used. Correction is required. See MPEP § 608.01(b).

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Insulated Fluid Cooled Electrosurgical Probe.

7. The disclosure is objected to because of the following informalities: Proper headings should be used throughout the specification (see below Arrangement of the Specification).

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

8. The disclosure is objected to because of the following informalities: **(a)** On page 8 lines 2 and 20, the reference number 36, used to indicate fluid passage/s, is inconsistent with the previous numbering of 26, where the reference number 36 has been associated with the inner insulating layer. **(b)** Also, on page 9 line 10, cavity 26 is inconsistent with the previous reference numbering of 24, where the reference number 26 has been associated with fluid passage.

Appropriate correction is required.

9. The disclosure is objected to because of the following informalities: Beginning with paragraph 5 on page 6 and ending with the last paragraph on page 9, the specification does not clearly indicate which Figures are being referenced.

Appropriate correction is required.

Claim Objections

10. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 line 10 states that the shaft has a distally closed hollow body. Claim 5 repeats this limitation.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 is vague and indefinite because it is unclear how hollow space can have the same diameter as an electrode or insulator contained within.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 1-5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Maguire et al. (5,913,854).

With respect to claim 1, Maguire et al. teaches the claimed surgical probe (Fig. 1, #2) comprising a handle (Fig. 1, #4) and a shaft (Fig. 1, #6) which is connected to the handle (column 3, lines 43-44) and has two axially mutually spaced electrodes (one or more electrodes along the shaft, column 1, lines 33-34), of which an electrode nearer the handle forms a proximal electrode and the other electrode which is far from the

handle forms a distal electrode (Fig. 1, #18, shows an electrode nearer to the handle than the adjacent, distal, electrode), wherein the electrodes respectively form an outside surface of the shaft (electrodes on the outside surface of the shaft, Fig. 1, #18) and are separated from each other by an insulator (alternating electrodes and polymer sections, column 4, lines 3-5), wherein the outside diameter of the two electrodes and the outside diameter of the insulator are approximately equal (approximately equal outside diameters of adjacent electrode and polymer sections, Fig. 2, #18 and #24) and wherein the shaft has a fluid passage for a cooling fluid, which extends in the interior of the shaft from the handle into the distal electrode (a handle with a fluid port which permits cooling fluid to be directed through shaft to cool electrode, column 3, lines 60-63), characterized in that the shaft has a distally closed hollow body which is connected to the handle and forms the distal electrode (a fluid passageway so that cooling fluid after reaching the distal end of the tip section of the catheter can be returned to the source so the fluid does not flow into the body but rather recirculates, column 5, lines 15-19), carries the insulator as well as the proximal electrode (shaft with electrodes and polymer sections, insulator, Fig. 2, #10) and an insulating layer which is arranged in the radial direction between the hollow body and the proximal electrode (PTFE, insulating layer, could be used to cover the inner surface of the electrode and shaft and not impede heat transfer between the cooling fluid and electrode, column 2, lines 4-9).

With respect to claim 2, Maguire et al. teaches the insulating layer arranged both between the hollow body and the proximal electrode and also between the hollow body

and the insulator (PTFE could be used to cover the inner surface of the electrode and shaft and not impede heat transfer between the cooling fluid and electrode, column 2, lines 4-9).

With respect to claim 3, Maguire et al. teaches that the insulating layer is formed by shrink tube (column 2, lines 4-9). It is well known in the art that shrink tube is manufactured from thermoplastic material such as PTFE.

With respect to claim 4, Maguire et al. teaches that the proximal electrode is formed by a metal tube of a diameter which is substantially equal over its length and of substantially equal wall thickness (column 6, lines 48-50).

With respect to claim 5, Maguire et al. teaches that the hollow body is closed at its distal end (a fluid passageway so that cooling fluid after reaching the distal end of the tip section of the catheter can be returned to the source so the fluid does not flow into the body but rather recirculates, column 5, lines 15-19).

With respect to claim 8, Maguire et al. teaches that in the region of the distal electrode the hollow body is of an outside diameter which is approximately equal to the outside diameter of the proximal electrode or of the insulator (approximately equal distal hollow body diameter to the outside diameter of the proximal electrode or the insulator, Figs. 1 and 2).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maguire et al. (5,913,854) in view of Lalonde (2002/0120258).

With respect to claim 6, Maguire et al. discloses the invention set forth above but fails to teach the fluid passage that extends in the hollow body to the closed end thereof and is of a diameter which is substantially equal throughout as in the instant claimed invention.

However, Lalonde teaches a distally closed tube for conveying fluid that may have a varying range of dimensions, such as length and cross-sectional shape (distally closed outer tube, Fig. 2, #201, and page 2, paragraph [0020]), which includes a hollow interior with a substantially equal diameter throughout.

It would have been obvious to one of ordinary skill in the hand-held electrosurgical art to have modified Maguire et al. with a hollow interior with a substantially equal diameter throughout as taught by Lalonde because it would have enabled the electrodes to be more efficiently cooled by way of a cooling fluid through a fluid passage (column 1, lines 41-47).

With respect to claim 10, Maguire et al. discloses the invention set forth above but fails to teach a hose in the interior of the fluid passage with a mouth opening in the proximity of the closed distal end of the fluid passage, which hose is so arranged and connected that a cooling fluid is to be passed through the hose into the proximity of the distal end of the fluid passage, there issues from the mouth opening of the hose and

can flow back between the hose and the wall of the fluid passage to the proximal end of the shaft as in the instant claimed invention.

However, Lalonde teaches arranging tubes to create a plurality of lumens for the flow of cryogen, where the tubes are arranged to create a closed loop flow path for cryogen such that it circulates through the catheter during operation of the device to flow from the supply through to the tip, and a vacuum return lumen, through which cryogen eventually flows back from the tip (Fig. 2 and page 2, paragraph [0023]).

It would have been obvious to one of ordinary skill in the hand-held electrosurgical art to have modified Maguire et al. with an interior hose in the fluid passage with a mouth opening in the proximity of the closed distal end of the fluid passage, which hose is so arranged and connected that a cooling fluid is to be passed through the hose into the proximity of the distal end of the fluid passage, there issues from the mouth opening of the hose and can flow back between the hose and the wall of the fluid passage to the proximal end of the shaft as taught by Lalonde because it would have enabled a cooling fluid return passageway so that cooling fluid, after reaching the distal end of the tip section of the catheter, can be returned to the source so that the cooling fluid does not flow into the body but rather recirculates.

19. Claim 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maguire et al. (5,913,854) in view of Klicek (5,221,281).

With respect to claim 7, Maguire et al. discloses the invention set forth above but fails to teach the hollow body shaped to a point at its distal end as in the instant claimed invention.

However, Klicek teaches a tip on the distal end of the tube (column 3, lines 17-19).

It would have been obvious to one of ordinary skill in the hand-held electrosurgical art to have modified Maguire et al. to include the tip on the distal end of the tube of Klicek because the distal tip of Klicek facilitates the insertion of the hollow body into tissue, which are both intended uses of the devices.

With respect to claim 9, Maguire et al. discloses the invention set forth above but fails to teach the hollow body is of a smaller diameter in the region of the insulator and the distal electrode than in the region of the proximal electrode as in the instant claimed invention.

However, Klicek teaches an electrosurgical configuration wherein the tube is tapered from a smaller diameter at the distal end to a larger diameter at the proximal end (Fig. 4, and column 4, lines 53-56).

It would have been obvious to one of ordinary skill in the hand-held electrosurgical art to have modified Maguire et al. with a smaller diameter in the distal region than in the proximal region as taught by Klicek because it would have enabled the distal region to be inserted easier into tissue.

20. Claim 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maguire et al. (5,913,854) in view of Crites et al. (3,568,660).

With respect to claim 11, Maguire et al. discloses the invention set forth above but fails to teach that at its proximal end the shaft is connected to the handle and is there partially embedded in sealing material in such a way that the tube forming the proximal electrode is completely embedded at its proximal end in the sealing material while the proximal end of the hollow body projects from the sealing material as in the instant claimed invention.

However, Crites et al. teaches a handle fitted over the cylinder and an electrically insulating epoxy applied over the exposed surface of the cylinder and a surface of the handle with the proximal ends of the conductors soldered to the conductors (column 5, lines 31-46).

It would have been obvious to one of ordinary skill in the hand-held electrosurgical art to have modified Maguire et al. with electrically insulating epoxy applied over the exposed surface of the cylinder and a surface of the handle with the proximal ends of the conductors soldered to the conductors as taught by Crites et al. because it would have enabled the proximal electrode to be preferably electrically contacted within the sealing material.

With respect to claim 12, Maguire et al. discloses the invention set forth above but fails to teach that the proximal electrode is electrically contacted within the sealing material as the instant claimed invention.

However, Crites et al. teaches the proximal ends of the conductors are soldered to the conductors (column 5, lines 45-46).

It would have been obvious to one of ordinary skill in the hand-held electrosurgical art to have modified Maguire et al. with proximally soldered ends as taught by Crites et al. because it would have enabled the proximal electrode to be electrically contacted within the sealing material.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John R. Di Cicco whose telephone number is (571) 270-5039. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on (571) 272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JRD

JOSEPH DEL SOLE
SUPERVISORY PATENT EXAMINER

9/4/07